PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

CATHERINE, Alain
Cabinet HARLE et PHELIP
7 rue de Madrid
F-75008 PARIS
FRANCE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	10.04.2006
Applicant's or agent's file reference: P852PCT2	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2005/001395	07.02.2005	06.02.2004

Applicant: INSERM (INSTITUT NATIONAL DE LA SANTE ET...) et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Moreno, R

Tel. +49 89 2399-2658

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P852PCT2	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2005/001395	International filing date *(day/month/year)* 07.02.2005	Priority date *(day/month/year)* 06.02.2004
International Patent Classification (IPC) or national classification and IPC INV. G01N33/569 C07K7/00		
Applicant INSERM (INSTITUT NATIONAL DE LA SANTE ET...) et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06.09.2005	10.04.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Weijland, A Telephone No. +49 89 2399-7490

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2005/001395

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-54 as originally filed

   Sequence listings part of the description, Pages

   1-6 as originally filed

   Claims, Numbers

   1-28 as originally filed

   Drawings, Sheets

   1/10-10/10 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15, 20-28
	No:	Claims	16-19
Inventive step (IS)	Yes:	Claims	22-24
	No:	Claims	1-21, 25-28
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.
PCT/EP2005/001395

The following documents (D) are referred to in this report; the numbering will be adhered to the rest of the procedure:

D1: WO-A-02053587
D2: WO-A-0208287

1. Novelty (Article 33(2) PCT)

1.1 The subject matter of claims 16-19 is anticipated by D1 and is therefore not novel.

D1 (abstract; page 16, paragraphs 1-3; Figure 3; page 18, second and third paragraph) describes a polypeptide capable of forming a structure to an intermediate state of GP41 and its use as part of a vaccine ("vaccine..comprising the amino acid sequence SWSNKS" according to claim 16) for preventing and treating HIV-mediated infections. Antibodies are raised against these peptides and can be used for passive immunisation. Said polypeptide can also be used in an ELISA to detect anti-gp41 antibodies present in the serum of individuals.

1.2 The subject matter of claims 1-15 and 20-28 is not disclosed in the prior art documents and can therefore be considered as novel.

2. Inventive Step (Article 33(3) PCT)

2.1 Peptides comprising the amino acid sequence of claim 1, which differ at two positions from the peptide cited in D1, would not involve an inventive step, since these mutations **fall outside the effective core region** "SWSNKS" (as defined on page 45 lines 29. 30 of the application) and therefore, do not bring along any unexpected effect whatsoever. Therefore, said peptides (claims 1-3) or pharmaceutical compositions (claims 4-7), vaccines (claims 8-19), methods of screening (claims 20, 21), in vitro assessment (claim 25), use of a ligand or polypeptide (claims 26 and 27) or antibody (claim 28) which involve somehow these peptides do not involve an inventive step.

2.2 D2 is considered as the closest prior art document. D2 (abstract; page 31, fourth paragraph; example 10; claims 1, 16, 17, 37, 39, 51, 61) describes targeting complexes comprising Nkp44 or a functional fragment thereof, used as therapeutic agents for the treatment of pathologies associated with viral infections, such as HIV. Enhancement of lysis of infected cells is blocked by a polyclonal antibody to Nkp44. Despite that Nkp44 is known, its ligand Nkp44L or a sequence related ligand is not brought into relation with HIV. Therefore, claims 22-24 related to the use of Nkp44L in a method for the screening of compounds in a disease linked to HIV would appear to involve an inventive step.